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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,194	06/16/2000	Susan J. Kirst	10147-25 (MBIO99-054)	2288

570 7590 03/01/2002

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EXAMINER	
TAYLOR, JANELL E	
ART UNIT	PAPER NUMBER
1634	11

DATE MAILED: 03/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/596,194	Applicant(s) KIRST ET AL.	
	Examiner Janell Taylor Cleveland	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 26, 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,16-18 and 24-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,16-18 and 24-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

The specification is objected to. The specification and claims include a reference to an ATCC number. It is required that the specification recite the following elements under CFR §1.801-1.809 (see also MPEP, Appendix R, Biotechnology Section.) For each deposit made, the specification shall contain: a) the accession number of the deposit; b) the date of the deposit; c) a description of the deposited biological material sufficient to specifically identify it and to permit examination; and d) the name and address of the depository.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the fully disclosed SEQ ID NOS, as well as some larger fragments, and complements thereof, does not reasonably provide enablement for any fragment of any size which may selectively hybridize to the nucleic acids of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. In particular, the way claim 18 is presently worded, any size fragment capable of hybridizing to the sequences of those in claim 1 is

claimed. This would mean fragments as small as one nucleotide, 2, 3, or several hundred. The specification provides no guidance for how to make these fragments, or how to use these fragments in a kit. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the specific and complete SEQ ID NOS given above, the skilled artisan cannot envision the detailed chemical structure of *fragments* of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Therefore, only the specific SEQ ID NOS given above, not the complementary fragments, meet the written description provision of 35 USC 112, first paragraph.

2. Claims 1, 3-7, 16-18, and 24-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The isolated nucleic acids of the claims include any sequence having at least 90% identity to the sequence found in SEQ ID NO: 59, 60, 61, and 63. Furthermore, the claims recite nucleotide sequences which are "complementary" to the stated sequence. The specification does not define complementarity as being limited to only full complements, however, so this may include nucleic acids which are 1%, 10%, 20%, etc. homologous. Since the claims do not include any *functional limitation*, allelic variants which have different functions from that of the stated sequences are included in the breadth of this claim. The specification has taught only SEQ ID NOS 59-63. The specification has not, however, conveyed that at the time of filing applicants were in possession of a representative number of nucleic acid molecules having the property of having any level of sequence complementarity over any portion of SEQ ID NOS: 59-63. It is noted that this aspect of the rejection may be overcome by amendment of the claims to recite a nucleotide sequence fully complementary to any of the nucleotide sequences listed. Furthermore, the claims as written include nucleic acid molecules having 90% or greater identity to the given nucleotide sequences, and large fragments of the sequence (such as 400 bases). A *functional activity* for the nucleic acid molecule itself is not set forth in the claims. Accordingly, the claims are inclusive of nucleic acid molecules which are allelic variants and which encode for proteins lacking the

functional activity of TANGO 332. The specification has not identified any allelic variants and which encode for proteins lacking the functional activities of TANGO 332. The specification has not identified any allelic variants of TANGO 332 having biological activities distinct from wild-type protein. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules. This part of the rejection may be overcome by reciting that the nucleic acid molecules code for a polypeptide which retains the functional activity of the TANGO 332 molecule.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "an adequate written description of DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed invention." The limited information provided in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of a full length genomic sequence encoding allelic variants of TANGO 332 having any functional activity, or of the broad genus of nucleic acids having any level of sequence

complementarity with SEQ ID NOS: 59-63. Therefore, the written description requirement has not been satisfied for the claims are they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 USC 112, 1st Paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-7, 16-18, and 24-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to ATCC accession number PTA-151. It is not clear, however, from the claims or from the specification, what this cDNA clone encodes. Because it is listed in the specification with a large number of SEQ ID NOS, and because it is not clear which ATCC number belongs to which sequence, it is not clear what this clone is or what it contains. This could be rectified by amending the claims and/or specification to clearly recite that PTA-151 corresponds to TANGO 332. Appropriate correction is required.

5. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 is a kit claim which contains instructions for use. It is not clear, however, what the kit is being used for, and therefore one of ordinary skill in the art would not be appraised of what the instructions might contain. If the nucleic acids of the kit are primers or probes, it is suggested that the claim be amended to recite this,

and that the instructions for use are comprised of instructions for amplifying and/or detecting.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Manheim Catalog (Biochemicals Catalog, 1997, page 95).

The claim is drawn to a kit comprising a compound which selectively hybridizes to the nucleic acid molecule of claim 1 and instructions for use.

The Boehringer Manheim catalog teaches a hexanucleotide mix which is a mixture of hexamer nucleotides of all possible sequences for random primed DNA labeling. (See second item on page.) This would have included multiple sequences which would have been capable of selectively hybridizing to the nucleic acid molecules of claim 1.

Summary

The specification is objected to. Claims 1, 3-7, 16-18, and 24-40 are rejected under 35 U.S.C. 112, first paragraph and second paragraph. Claim 18 is rejected under 35 U.S.C. 102(b). No claim is allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 872-9306 or 872-9307 (after final). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

February 21, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600